

EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESAL PRICE)	
LITIGATION)	MDL No. 1456
)	Civil Action No. 01-12257-PBS
)	
THIS DOCUMENT RELATES TO:)	Hon. Patti Saris
)	
<i>United States of America ex rel. Ven-a-Care of</i>)	Magistrate Judge Marianne B. Bowler
<i>the Florida Keys, Inc., v. Abbott Laboratories,</i>)	
<i>Inc.,</i>)	
CIVIL ACTION NO. 06-11337-PBS)	

**UNITED STATES’ OPPOSITION TO DEFENDANT ABBOTT LABORATORIES,
INC.’S RENEWED MOTION TO COMPEL EVIDENCE WITHHELD UNDER
THE DELIBERATIVE PROCESS PRIVILEGE**

In its Motion to Compel, defendant Abbott Laboratories Inc. (Abbott) contends that the United States should be prohibited from asserting the deliberative process privilege in this case since its claims against Abbott “put [the Government’s] knowledge and deliberations at issue.” In the alternative, Abbott claims that its particularized need for the privileged documents in the context of this case outweighs the public interest in protecting the Government’s deliberative processes from disclosure. Abbott further argues that the United States has not asserted the privilege in a procedurally and substantively appropriate manner.

All three of Abbott’s contentions are baseless and should be rejected by this Court. The documents listed on the United States’ privilege logs are collateral to the critical issues in this case. This fact fatally undermines (1) Abbott’s assertions that the Government “waived” its deliberative process privilege by bringing this case, or (2) that Abbott’s need for the documents outweighs the Government’s interest in preserving the confidentiality of its deliberative

processes. Furthermore, the United States has complied with all substantive and procedural requirements in asserting the deliberative process privilege with respect to the documents on its privilege logs, and Abbott's contention to the contrary contravenes well established case law in this and other Circuits. Abbott's Motion should be denied in its entirety.

BACKGROUND

I. PROCEDURAL HISTORY

In late 2003, the United States received several subpoenas from the defendants in this and another multi-district litigation pending in this district: MDL Nos. 1456 and 1430. The subpoenas were directed to both the Department of Health and Human Services (HHS) and the several regional Medicare carriers that HHS uses to administer the Medicare program ("Carriers"). In response to these subpoenas, in 2004, the United States produced approximately 95,000 pages of documents from the Carriers, and approximately 22,000 pages of documents from HHS itself. After discussions between the United States and the defendant manufacturers, the United States later produced privilege logs, both from the Carriers and from the Centers for Medicare and Medicaid Services (CMS), and asserted a claim of privilege over 600 documents from this production, many of which were withheld on the basis of the deliberative process privilege. These privilege assertions were never challenged in Court by any of the parties in the two MDL proceedings.

After the United States intervened as to Abbott, Abbott propounded a Request for Production (RFP) seeking all of the documents the government withheld from its response to the 2003 subpoenas on the grounds of the deliberative process privilege. *See Ex. 1, Abbott's First Set of Requests for Production*, p. 27, RFP No. 126. In response to Abbott's request, the United

States undertook an additional review of the documents withheld from its earlier production. After completing this review, the United States agreed to release all or part of approximately 200 documents from the 2004 Carrier and CMS privilege logs. The updated CMS and Carrier privilege logs contain entries for 451 documents, a substantial majority of which have been withheld on the basis of the deliberative process privilege.¹ Abbott has now moved to compel production of all of the documents on these logs that have been withheld solely on this basis.

In addition, Abbott has propounded a number of RFPs seeking documents maintained by the HHS Office of Inspector General (OIG). Specifically, Abbott has sought the underlying work papers and files associated with a set of Inspection Reports and Audits that various OIG offices have published over the last 25 years. *See* Ex. 1, *Abbott's First Set of Requests for Production*, pp. 13-14, RFP Nos. 20-21, Schedule A. The United States has produced a substantial number of responsive documents in response to Abbott's requests, but has asserted the deliberative process privilege over approximately 240 responsive documents. Abbott's Motion to Compel seeks documents from this log as well.

II. GOVERNING PRINCIPLES OF THE DELIBERATIVE PROCESS PRIVILEGE

The deliberative process privilege is an "ancient privilege [that] is predicated on the recognition that the quality of administrative decision making would be undermined if agencies were forced to operate in a fishbowl." *Dow Jones & Co., Inc. v. Department of Justice*, 917 F.2d 571, 573 (D.C. Cir. 1990) (internal quotation marks and citation omitted). The privilege is

¹ The attached privilege logs include documents withheld pursuant to the attorney-client privilege and the work product doctrine. Abbott's Motion to Compel does not challenge the United States' withholding of documents on these bases; the Motion to Compel is limited to documents withheld solely on the basis of the deliberative process privilege.

designed to protect inter-agency and intra-agency deliberations and advice, the disclosure of which would be injurious to the federal government's decision-making functions. *Petroleum Info. Corp. v. United States Dep't of Interior*, 976 F.2d 1429, 1433 (D.C. Cir. 1992). The Supreme Court has held that exposing such materials to outside review would tend to inhibit the candid discussion necessary to effective government. *See NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150-51 (1975); *EPA v. Mink*, 410 U.S. 73, 87 (1973).

The central theme of the well developed body of case law interpreting and applying the deliberative process privilege has been the need to safeguard the integrity of the internal debates and discussions necessary to responsible governmental decision making. As the D.C. Circuit explained in *Coastal States Gas Corp. v. United States Dep't of Energy*, 617 F.2d 854, 866 (D.C. Cir. 1980), the deliberative process privilege protects the "give and take" process of effective government by:

- 1) Ensuring that subordinates in an agency can be candid with decision makers and can provide "uninhibited opinions and recommendations without fear of later being subject to public ridicule or criticism";
- 2) Protecting "against premature disclosure of proposed policies before they have been finally formulated or adopted"; and
- 3) Guarding "against confusing the issues and misleading the public by dissemination of documents suggesting reasons and rationales for a course of action which were not in fact the ultimate reasons for the agency's action."

(citing *Jordan v. United States Dep't of Justice*, 591 F.2d 753, 772-74 (D.C. Cir. 1978)); accord *United States Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8 (2001) (The privilege "rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news.").

The deliberative process privilege protects evidence from disclosure if it is both pre-decisional and deliberative in nature, containing opinions, recommendations, or advice about agency decisions. *See Renegotiation Bd. v. Grumman Aircraft Eng'g Corp.*, 421 U.S. 168, 184 (1975). Generally, pre-decisional documents will be created prior to the agency decisions to which they contributed; however, it is important to recognize that agency decision making is a continuous process, and documents containing protected recommendations or advice may not ripen into a specific agency decision – and indeed, may be subsequent to related agency decisions. *See Sears, Roebuck & Co.*, 421 U.S. at 151 (“Agencies are, and properly should be, engaged in a continuing process of examining their policies; this process will generate memoranda containing recommendations which do not ripen into agency decisions, and the lower courts should be wary of interfering in this process.”). Internal agency documents are "deliberative" when they reflect the "give-and-take" of the consultative/deliberative process. *Coastal States*, 617 F.2d at 866; *American Fed’n of Gov’t Employees, AFL-CIO, v. United States Dep’t of Health and Human Servs.*, 63 F.Supp.2d 104, 107 (D. Mass. 1999).

The deliberative process privilege is not absolute. After concluding that the privilege has been properly invoked, the court must balance the public interest in protection of the deliberative process against the particularized need for the information as evidence in the case before it. *See Comm. for Nuclear Responsibility, Inc. v. Seaborg*, 463 F.2d 788, 791 (D.C. Cir. 1971); *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena*, 40 F.R.D. 318, 327 (D.D.C. 1966), *aff’d*, 384 F.2d 979 (D.C. Cir. 1967); *Scott v. PPG Indus., Inc.*, 142 F.R.D. 291, 294 (N.D. W. Va. 1992). To compel disclosure, the claimant must make “a showing of necessity sufficient to outweigh the adverse effects the production would engender.” *Carl Zeiss*, 40 F.R.D. at 328-29.

One of the most oft cited statements of the factors to be considered in balancing the requisite interests is found in *In re Franklin Nat'l Bank Sec. Litig.*, 478 F.Supp 577, 583 (E.D.N.Y. 1979). When balancing the Government's interest in protecting its deliberative processes against the defendant's need for the evidence, Judge Weinstein articulated the following considerations:

(I). the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

Id. (internal citations omitted).

ARGUMENT

I. THE DOCUMENTS ABBOTT SEEKS TO COMPEL ARE COLLATERAL TO THE CORE ISSUES IN THIS CASE

Abbott's Motion to Compel rests on a fundamentally flawed premise – namely, that the allegations in the United States' complaint place the Government's deliberative processes at issue in this litigation. Seeking to shift attention from its own conduct, Abbott contends this case turns on why the Government designed or continued to use a drug reimbursement system that relied on AWP. This case, however, is ultimately about Abbott's conduct – specifically, about Abbott's practice of reporting fraudulent prices to third-party compendia, and Abbott's scienter in reporting those fraudulent prices. In other words, this case has nothing to do with whether AWP-based drug reimbursement systems are flawed; it is about how Abbott knowingly abused the reimbursement systems that were in place during the period covered by the United States' complaint. The Government's deliberative processes, as reflected in the documents that Abbott

has moved to compel, are irrelevant to the specifics of Abbott's conduct, and thus irrelevant to the core issues of the complaint.

Abbott's ability to prevail on its first two arguments – namely, that (1) the United States has waived its deliberative process privilege by bringing this case, and/or (2) that Abbott's particularized need for these documents outweighs the governmental interest in preserving the privilege – rests wholly on its ability to articulate a credible need for these documents in developing its defenses to the specific allegations in this case. As discussed in Section II, *infra*, however, wholesale waiver of the deliberative process privilege is dependent on the governmental entities' subjective motivation being *the* issue in a given piece of litigation, such as in a Title VII context. Such is not the case here. Abbott fares no better when the balancing test is applied to its demands. The balancing test weighs the proponents' need for documents in the context of the issues in the case against the governmental and public interest in retaining the documents. Abbott's inability to demonstrate a need for these documents thus also fatally undermines this argument. As detailed below, an assessment of the United States' core contentions in the instant case, brought pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 (FCA), and common law fraud, reveals the fundamental irrelevance of the documents sought to Abbott's defenses in this case.

A. The Documents Are Irrelevant to the FCA Causes of Action

The First and Second Causes of Action of the United States' complaint seek relief under several provisions of the FCA. *See* Ex. 2, United States' Complaint, pp. 26-27, ¶¶ 102-107.

Abbott contends that the government's deliberative processes, as reflected in the documents that it has moved to compel, may shed light on what HHS employees "knew, understood, or agreed to

in the area of drug reimbursement,” and that a resolution of these issues is relevant to the disposition of the Government’s allegations in this case.

The flaw in Abbott’s position is that what particular government officials knew, understood, or agreed to in the area of drug reimbursement is not relevant to a defense of an FCA claim unless that knowledge, understanding, or agreement was communicated to Abbott. The fact that a particular CMS, carrier, or OIG official knew or understood certain facts about drug reimbursement is not, in and of itself, relevant, because “government knowledge” is not a defense under the FCA. *See United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) (“that the relevant government officials knew of the falsity is not in and of itself a defense.”).

In certain circumstances, evidence of government knowledge *may* be relevant to the question of whether the defendant possessed the requisite scienter under the FCA. Under the FCA, to negate scienter, Abbott must show (1) that the Government was fully informed by Abbott of the conduct at issue and (2) that the Government *approved* of the conduct at issue. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 861178, at *7 (D. Mass. March 22, 2007) (denying motion to dismiss California False Claims Act claim, noting that government approval of the particulars is necessary to negate scienter). Mere acquiescence is not enough to constitute approval negating FCA scienter. *See United States ex rel. Tyson v. Amerigroup*, 2007 WL 781729, at *20 (N.D. Ill. March 13, 2007) (denying defendant’s motion for new trial, noting that the proper test is whether the government knew and approved the particulars of defendant’s conduct, and that mere acquiescence, rather than approval, by government employees is not sufficient to avoid FCA liability).

For a defendant to an FCA action to establish that government knowledge and approval negates scienter, the defendant must demonstrate that it reasonably believed that it (1) fully disclosed the conduct at issue and (2) was complying with its contractual or regulatory obligations based upon representations of approval made to it by appropriate government officials. Abbott has not come close to establishing the threshold element of a government knowledge-based defense, *i.e.*, that it fully disclosed and informed the government of the conduct alleged in the complaint. The United States has issued several discovery requests for evidence of such disclosures and has not received any such evidence to date. *See* Ex. 3, *United States' First Set of Requests for Production*, pp. 8-9, RFP Nos. 3-8.

Even if Abbott argues that the government obtained the information from other sources, what government officials knew, understood, or agreed to with respect to drug reimbursement can only be relevant to Abbott's defense under the FCA if that knowledge, understanding, or agreement was shared with Abbott. The documents listed on the attached privilege logs have never been shared with anyone outside of the Government and its agents, and thus have obviously never been shared with Abbott. Indeed, none of the documents on any of the logs refer to any communications between the government and Abbott concerning drug reimbursement, a fact that (1) is apparent from the logs themselves (describing the documents) and the attached declarations, and (2) could be confirmed through an *in camera* review of the documents.

Given these facts, Abbott cannot make a credible argument that the deliberative processes contained in the documents on the attached privilege logs could possibly be construed to undermine *Abbott's* scienter under the FCA.

B. The Documents Are Irrelevant to the Common Law Fraud Cause of Action

The Fourth Cause of Action in the United States’ complaint concerns common law fraud. The United States alleges that it was justified in relying on Abbott’s reported AWP’s, as such reliance is an element of the cause of action for common law fraud. *See Ex. 2, United States’ Complaint*, p. 28, ¶¶ 113-115. Abbott’s Motion never squarely addresses the issue of justifiable reliance as an element of common law fraud, but is replete with assertions that appear to implicate justifiable reliance, such as the notion that “the Government’s knowledge of spreads and its deliberations about using published AWP’s despite knowing of large spreads is obviously relevant to a fraud case.” *See Def’s Memorandum (Memo.)* at 6.

Abbott’s arguments fail because of a fundamental misapprehension of the nature of the justifiable reliance element in the United States’ common law fraud cause of action. It is well established that “men must turn square corners when dealing with the government.” *Heckler v. Community Health Servs.*, 467 U.S. 51, 63 (1984) (internal citation omitted). Thus, it follows, that the relevant inquiry is *not* whether the government was justified in using AWP as a benchmark for reimbursement in general. The relevant question is whether the United States, given the statutory and regulatory system in place, justifiably relied upon Abbott’s reported AWP’s for the drugs at issue in this case in reimbursing claims for those Abbott products. As detailed below, the answer to that question is yes.

During the relevant time period, Congress and the Secretary of HHS have limited Medicare payments to the lower of the estimated acquisition cost or the national average wholesale price of a drug. 56 Fed. Reg. 59502, 59621 (Nov. 25, 1991) (final rule). This regulation governed Part B drug payments until 1997, when Congress amended the Medicare Act

and set Part B drug payments at 95 percent of the average wholesale price. *See* Pub. L. 105-33, 111 Stat. 462-463 (1997). The Secretary amended the Medicare regulations in 1998 to conform with the Balanced Budget Act amendment and, effective January 1, 1999, Medicare paid the lesser of the supplier's actual charge or 95 percent of the national average wholesale price. 63 Fed. Reg. 58814, 58905 (Nov. 2, 1998). This payment system remained in place until 2003, when Congress passed the Medicare Prescription Drug, Improvement and Modernization Act (MMA). Pub L. 108-173, 117 Stat. 2066 (2003).

During the same time frame, a majority of State Medicaid agencies have likewise incorporated published AWP's or Wholesale Acquisition Cost (WAC) into their reimbursement formulae. *See* Ex. 2, *United States' Complaint*, p. 14, ¶¶ 42-44.

This Court has held that the term "average wholesale price," as a statutory and regulatory term, *had a plain meaning* during this time frame. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 287 (D. Mass. 2006) (emphasis added) (holding that "the term 'average wholesale price' in the Medicare statute is not a term of art for any price the pharmaceutical industry places in the industry publication and will be construed under the plain language doctrine of statutory construction"). Under the systems that were in place for the reimbursement of generic drugs during the period covered by the United States' complaint, Abbott was obligated to report prices for its drugs that would ensure that published AWP's were consistent with the plain meaning of the regulatory term. Reliance under these circumstances was established by statute and regulation, not by a specific agency decision that Abbott's customers deserved to be reimbursed based on whatever AWP Abbott chose to report, regardless of its truth or falsity.

The government's complaint focuses on very specific pricing and marketing conduct related to drugs comprising 45 NDCs and is based on facts uncovered during a fraud investigation. Government documents containing macro-level discussions about the Medicare and Medicaid reimbursement systems for generic drugs between 1991 and 2003 are not relevant to Abbott's defense of the United States' common law fraud claim. The privileged documents Abbott seeks are relevant only if they relate to the issue of whether the United States justifiably relied on Abbott's price representations (1) for the drugs at issue or (2) Abbott drugs generally. Abbott, however, has not shown how particular documents on the United States' privilege logs involved Governmental decisions about whether to reimburse the *Abbott* drugs at issue in the case at some amount other than an amount based on *Abbott's* reported prices. Abbott points to nothing on the United States' privilege logs that it believes contain Abbott-specific deliberations or determinations about whether to reimburse Abbott's subject drugs at any particular amount. The documents on the OIG log relate to pre-decisional deliberations concerning the findings of specific Inspections and Audits, and in no way involve decisions about the bases upon which to reimburse specific claims. The great bulk of documents on the CMS and Carrier logs similarly focus on macro-level policy issues. There are no documents on any of the three logs that could afford Abbott a reasonable defense to its common law fraud claim.

**II. THE COLLATERAL NATURE OF THE DOCUMENTS AT ISSUE
ELIMINATES ANY ARGUMENT OF BLANKET WAIVER, AND THE
BALANCING TEST IS DECIDEDLY IN THE UNITED STATES' FAVOR**

**A. There is no Blanket Waiver of the Deliberative Process Privilege Based on
the United States' Allegations in this Case**

In light of Section I above, Abbott's contention that the United States has comprehensively waived its deliberative process privilege by intervening in the instant against

Abbott is completely unsupportable in the law. The United States' allegations in the instant case do not place at issue the subject matter of any of the deliberations contained on its privilege logs, and a wholesale waiver in such circumstances would be unprecedented.

Courts have consistently rejected the argument that the deliberative process privilege is waived simply because the government is a plaintiff in an enforcement action. *See Landry v. FDIC*, 204 F.3d 1125, 1136 (D.C. Cir. 2000); *United States v. Hooker Chemicals and Plastics*, 114 F.R.D. 100, 103 (W.D.N.Y. 1987). The only circumstances in which any courts have effected a blanket waiver of the privilege have been in circumstances where the governmental entity's subjective motivations were *the* issue in the litigation, such as in a Title VII context. *See In re Subpoena Duces Tecum Served on the Comptroller of the Treasury*, 145 F.3d 1422, 1425 (D.C. Cir. 1998) (privilege must give way when issues in case make deliberative processes the issue, as in Title VII discrimination cases). As described in Section I, *supra*, the allegations in the United States' complaint involve no such issue; this case is about Abbott's conduct, not about the United States' subjective motivations.

Even assuming, *arguendo*, that the "knowledge and deliberations" of the United States were at issue in this litigation, it would not follow that a blanket waiver of the United States' deliberative process privilege would be appropriate. Courts have routinely applied the "balancing test," described above, after concluding that the Government's knowledge or deliberations are *an* issue in the underlying litigation. *See Alexander v. FBI*, 186 F.R.D. 200, 206 (D.D.C. 1999) (finding government conduct and intent at issue before engaging in balancing analysis); *Department of Econ. Devel. v. Arthur Anderson & Co.*, 139 F.R.D. 295, 298-99 (S.D.N.Y. 1991) (same).

Further undercutting its own argument, Abbott's Motion cites cases that apply the fact-specific balancing test (rather than wholesale waiver) to the Government's invocations of the privilege. *See Def's Memo.* at 5. Nonetheless, Abbott persists in its claim that the United States should be barred from asserting the privilege with respect to future documents or testimony in this case, and its proposed order does not provide any alternative to such a sweeping ruling. *See Def's Memo* at 5-7; *Def's Proposed Order* at ¶ 2 (barring the United States from asserting the privilege in the future absent a Court order). Abbott is therefore asking this Court to apply the balancing test *now* to documents and testimony described in hypothetical future privilege logs and agency declarations the Court has never reviewed.

This suggestion runs completely contrary to case law. The balancing test clearly envisions a well-defined, individualized review of each assertion of the deliberative process privilege. *See In re Sealed Case*, 121 F.3d 729, 737 (D.C. Cir. 1997) ("each time the deliberative process privilege is asserted the district court must undertake a fresh balancing of the competing interests.") (internal quotation marks and citations omitted). It would be speculative in the extreme to apply an individualized balancing test to hypothetical documents or testimony over which over which the privilege may be asserted. The United States has not identified any case where courts undertook such an speculative exercise. This Court should assess the merits of the United States' privilege assertions on a document-by-document basis, and should reject Abbott's legally insupportable attempt to convert a factor-specific balancing inquiry into a black-letter rule.

B. The Balancing Test Favors the United States' Position

The appropriate manner in which the Court should assess the United States' privilege assertions is to balance the United States' interest in preserving the privilege against Abbott's need for the documents, in light of the specific issues involved in this case. Given the fundamentally collateral nature of the privileged documents to any of Abbott's defenses, Abbott's purported need for the documents should give way to the United States' interests in protecting its deliberative processes. An analysis of the various prongs of the balancing test bears this conclusion out.

The first two elements of Judge Weinstein's articulation of the balancing test are: (1) the relevance of the documents, and (2) the availability of other evidence enabling the opposing party to prove its claim or construct its defense. *See Franklin Nat'l Bank*, 478 F. Supp at 583. As was discussed *supra*, the documents contained on the United States' privilege logs themselves are simply not relevant to any defenses Abbott could raise to the allegations in the United States' complaint. A requesting party cannot, as a matter of law, demonstrate "need" in the absence of relevance, and the relevance of the privileged documents here are dubious at best. *See United States v. Farley*, 11 F.3d 1385, 1390 (7th Cir. 1993). Abbott cannot and does not argue that these non-public documents are somehow relevant to its scienter, and Abbott cannot show that any of these documents are pertinent to issues concerning the United States' reliance on Abbott's reported prices in reimbursing Abbott's subject drugs.

As to the second element of the test, i.e., the "availability of other evidence," the key point is the following – this case is about *Abbott's* conduct, not about the United States' system for the reimbursement of prescription drugs. Evidence relevant to Abbott's knowledge,

understanding, and conduct is much more likely to be found in Abbott's files than in the Government's. With the exception of the United States' claims data, it is unlikely the United States could produce any documents relevant to the core issues in the case that are not already in Abbott's possession.

The fifth element of the balancing test concerns the possibility of future timidity by government employees if the documents are disclosed.² See *Franklin Nat'l Bank*, 478 F. Supp at 583. This prong is directed to assessing the possibility of a chilling effect on candid and frank agency discussion if the deliberative processes at issue are disclosed to the public and used as fodder for litigation. Given the nature of the documents and processes at issue in Abbott's Motion to Compel, future timidity is a serious concern in this case.

The attached Government declarations clarify the specifics of this concern. The OIG log consists largely of documents generated pursuant to formal internal processes at the Office of Evaluation and Inspections (OEI), such as minutes of entrance and exit conferences and drafts of the OEI's publicly issued inspection reports. See Ex. 4, *Declaration of Robert Vito* (attached privilege log). Robert Vito, the Regional Inspector General, notes the critical role that the candid advice of staff plays in the formulation of work plans and the ultimate drafting of OEI reports. See *Id.* at p. 13. Documents directly analogous to those on the OIG log have been found to fall within the scope of the privilege in the past. In *Moye, O'Brien, O'Rourke, Hogan, & Pickert v.*

² The third and fourth prongs of the balancing test, less relevant to the instant case, concern the (3) seriousness of the litigation and (4) role of the government in that litigation. See *Franklin Nat'l Bank*, 478 F. Supp at 583. The Government is the plaintiff in this litigation, and the issues are undoubtedly serious. The Government's status as a plaintiff does not affect the United States' ability to assert the privilege – especially where, as here, the privileged documents are of dubious relevance to the defendant's case. See, e.g., *Landry*, 204 F.3d at 1136.

Nat'l R.R. Passenger Corp., the court found that the body of internal work papers generated by Amtrak's OIG in connection with financial and performance audits were covered by the privilege. 376 F.3d 1270, 1279 (11th Cir. 2004). In its decision, the court held that the privilege covered "the entire body of collaborative work performed by the auditors," including "the initial work plan for the audit describing its purpose and objectives as well as the methodologies and sampling techniques that will be used to gather and analyze audit data." *Id*; see also *Hamilton Sec. Group v. Department of Housing and Urban Dev.*, 106 F.Supp 2d. 23, 29-32 (holding that OIG draft audit materials were protected by deliberative process privilege). Release of the documents from the OIG privilege log would, as Mr. Vito's declaration states, chill the vigorous internal debate and discussion that characterizes the work of his and other OIG offices.

The documents contained on the CMS and carrier privilege logs come from a broader set of offices and sections within the agency than do the documents on the OIG log. However, the declaration from Leslie Norwalk, the acting Administrator of CMS, spells out quite clearly the concern within that agency about the possibility of a chilling effect upon agency deliberations if these documents are to be released. Ms. Norwalk's declaration articulates the key role that candid internal discussion plays in CMS's efforts to set policy consistent with the agency's controlling statutes, regulations, and objectives, and notes that her belief that CMS employees would feel constrained in offering candid advice if they lacked confidence that their views would be treated as confidential. See Ex. 5, *Declaration of Leslie Norwalk*, at 17-21.

In sum, the documents contained on the United States' privilege logs bear little if any relevance to Abbott's defenses to the allegations in the United States' complaint. However, as the attached declarations state, the release of these materials would likely have a chilling effect

on the internal deliberations necessary for effective agency action. The balance of these considerations tips heavily towards preserving the United States' privilege assertions.

III. THE UNITED STATES HAS COMPLIED WITH ALL PROCEDURAL AND SUBSTANTIVE REQUIREMENTS IN ASSERTING THE PRIVILEGE

Abbott complains that the United States has failed to support its privilege assertions in the procedural and substantive manner required. Abbott's complaints have no basis in the law of this or any other Circuit, and should be summarily rejected this Court.

A. The Attached Declarations are Timely as a Matter of Law

Abbott's initial complaint is that the United States was obligated to submit agency declarations supporting the United States' assertion of the deliberative process privilege at the time that the United States placed the documents on its privilege logs in response to Abbott's discovery requests. This contention runs contrary to the great weight of authority, which confirms the principle that declarations of agency personnel are only necessary when asserting a governmental privilege in court, in response to a motion to compel or in support of a motion for a protective order. *See In re Sealed Case*, 121 F.3d at 741 (White House was not obliged to "formally invoke its [executive] privileges in advance of the motion to compel;" it was sufficient that it said, in response to a subpoena, that it "believed the withheld documents were privileged."); *Huntleigh USA Corp. v. United States*, 71 Fed. Cl. 726, 727 (2006) (procedural requirements for privilege assertion are satisfied through the production of a declaration or affidavit by the agency head in response to a motion to compel); *Tri-State Hosp. Supply Corp. v. United States*, 226 F.R.D. 118, 134 n.13 (D.D.C. 2005); *In re Consol. Litig. Concerning Int'l Harvester's Disposition of Wis. Steel*, Nos. 81 C 7076, 82 C 6895 & 85 C 3521, 1987 WL 20408, at *7 (N.D. Ill. Nov. 20, 1987) (rejecting assertion that agency head's affidavit must be submitted

when privilege is first invoked); *Abramson v. United States*, 39 Fed. Cl. 290, 294 n.3 (1997) (“procedural requirements generally are satisfied through the production of a declaration or affidavit . . . in response to a motion to compel”); *Securities & Exch. Comm’n v. Downe*, 1994 WL 23141, at *5 (S.D.N.Y. Jan. 27, 1994) (unpublished opinion) (government meets its obligation regarding affidavit by filing it with its papers opposing motion to compel). Abbott does not point to a single First Circuit case holding that an agency declaration in support of an assertion of the deliberative process privilege is necessary at all, let alone that such a declaration must be submitted in response to a discovery request as opposed to in response to a motion to compel.

It should be noted that the above-cited holdings concerning the appropriate timing of an agency declaration make eminent practical sense. In the course of complex litigation, litigants routinely place documents on privilege logs and withhold such documents from production. Many such privilege notations are unchallenged by the opposing party. Until a litigant has actually sought judicial intervention to compel the production of documents withheld on the basis of the deliberative process privilege from a privilege log, it makes little sense to require senior agency officials to personally review the logged documents in order to formally invoke the privilege. Such a review would be exceptionally burdensome to the agency and quite possibly entirely academic to the litigation. In *Scott*, 142 F.R.D. 291, 293-94 (N.D. W. Va. 1992), the court noted that “it is ludicrous to suggest that the agency head rather than the EEOC’s litigation attorney should be required to invoke the deliberative process privilege in a deposition.” It is similarly inappropriate to require senior federal officials to be burdened with submitting

declarations formally invoking the deliberative process privilege over documents that may never be the subject of litigation.

The bulk of the cases Abbott cites in support of its argument that an agency declaration is required at the time that documents are placed on a privilege log do not stand for the propositions for which they are cited. *Mobil Oil*, a case cited heavily by Abbott, concerned a situation where the agency apparently did not submit an agency affidavit or declaration at all in response to a motion to compel. *See Mobil Oil Corp. v. Dep't of Energy*, 102 F.R.D. 1, 6 (N.D.N.Y. 1983). The court held that such a declaration was required, but did not address the issue of the appropriate timing for submitting such an affidavit. The *Grossman* case similarly did not squarely address the appropriate timing of an appropriate declaration, but noted that the purpose of such a declaration was to enable “the court to make an intelligent and informed judgment as to each requested piece of information” – thus suggesting that such declarations only need be produced in response to a motion to compel. *Grossman v. Schwartz*, 125 F.R.D. 376, 381 (S.D.N.Y. 1989). The portion of the Federal Claims Court’s decision in *Pacific Gas* case, cited by Abbott for the proposition that the Government’s failure to submit an affidavit at the time the documents were logged waived the privilege, was modified in a corrected opinion. *See Pacific Gas & Elec. Co. v. United States*, 71 Fed. Cl. 205, 208-09 (2006) (stating that there was no waiver of right to assert deliberative process privilege by waiting to produce agency affidavit in response to motion to compel, rather than earlier in the process, but that such affidavits would be subjected to “heightened scrutiny”). The same Court of Federal Claims, within two months of publication of the corrected *Pacific Gas & Electric* opinion, held that “the procedural requirements for asserting the privilege “are satisfied through the production of a declaration or

affidavit by the agency head, and produced in response to a motion to compel.” *Huntleigh*, 71 Fed. Cl. at 727.

In sum, the great bulk of authority addressing the issue holds that production of agency declarations in response to motions to compel is procedurally proper. Abbott’s contention to the contrary is both impractical and unsupported by the law, and should be rejected for both reasons.

B. The Documents on the United States’ Privilege Logs Satisfy the Substantive Requirements for Assertion of the Deliberative Process Privilege

Abbott also attacks the United States’ privilege assertions on substantive grounds, contending that the United States has failed to identify the decision to which certain documents relate and that it has improperly withheld certain draft documents. Abbott’s argument is vague and unfocused – other than citing several examples, it fails to note precisely which documents on the United States’ privilege logs it views as falling outside the scope of the privilege and for which reasons. Nevertheless, the United States will address this point.

Citing *Providence Journal Co. v. United States Dep’t of the Army*, 981 F.2d 552, 557, Abbott argues that the United States must identify, with respect to each document on its logs, the “specific agency decision to which the document correlates.” It is a misreading of both *Providence Journal* and the broader state of the case law to suggest that such an identification is required for the privilege to be asserted properly. Agency decision making is a complex process, and agencies often generate documents that may be prior to one agency decision, while being subsequent to other agency decisions. The Supreme Court has held as much:

Our emphasis on the need to protect pre-decisional documents does not mean that the existence of the privilege turns on the ability of an agency to identify a specific decision in connection with which a memorandum is prepared. Agencies are, and properly should be, engaged in a continuing process of examining their policies; this

process will generate memoranda containing recommendations which do not ripen into agency decisions; and the lower courts should be wary of interfering with this process.

Sears, Roebuck and Co., 421 U.S. at 151-52; *see also Moye*, 376 F.3d at 1280 (“contrary to the district court’s finding and the firm’s assertion, Amtrak need not cite to a specific policy decision in connection with which the audit work papers and internal memoranda were prepared in order for these documents to be protected from disclosure by the deliberative process privilege.”); *Access Reports v. United States Dep’t of Justice*, 926 F.2d 1192, 1196 (D.C. Cir. 1991) (internal memorandum prepared was protected by deliberative process privilege despite claim that it did not relate to any particular decision). *Providence Journal* itself notes that an agency “may” meet its burden of demonstrating that a document is pre-decisional by identifying the specific agency decision to which it relates; the case does not state that such identification is mandatory. *Providence Journal*, 981 F.2d at 559.

Indeed, the *Providence Journal* court later framed the following as “the appropriate judicial inquiry” when assessing claims of deliberative process privilege: “whether the agency document was prepared to facilitate and inform a final decision *or deliberative function* entrusted to the agency.” *Id.* at 560 (emphasis added). Certain of the documents on the United States’ privilege logs do not necessarily relate to final policy decisions, yet absolutely were prepared to inform “deliberative functions entrusted to the agency.” The OIG privilege log contains numerous documents relating to that organization’s deliberative functions, such as preliminary drafts of the reports and notes of entrance and exit conferences associated with the reports. Such documents may or may not have led to specific agency policy decisions – their

status as privileged does not depend on identifying any such decision. *See Moya*, 376 U.S. at 1280.

Many of the documents on the United States' privilege logs are drafts of agency statements, reports, or deliberations on a variety of issues. Drafts are inherently deliberative, and rarely relevant, as they do not constitute a final agency position or statement on any disputed issue. *See Grossman*, 125 F.R.D. at 385. Stated differently, drafts represent the personal opinion of the author, not yet adopted as the position of the agency. *See Judicial Watch, Inc. v. Clinton*, 880 F. Supp. 1, 13 (D.D.C. 1995), *aff'd*, 76 F.3d 1232 (D.C. Cir. 1996).

This Court has embraced the reasoning of the above-cited authorities in a relatively recent decision involving draft documents. *See AFL-CIO*, 63 F.Supp.2d at 108. Noting that "draft documents have frequently been held to be deliberative material," this Court went on to state that releasing the draft at issue in that case "would enable a careful reader to determine the substance of HHS's proposed changes," because the draft consisted of "the suggestions of individual agency employees as to what the final [document] should look like." *Id.* The Court concluded that release of the draft "would discourage candid discussion within the agency and thereby undermine HHS' ability to perform effectively its assigned function," and upheld the United States' privilege assertion over the document. *Id.* The rationale that this Court used in the *AFL-CIO* case is equally applicable to the drafts contained on the United States' privilege logs, and that rationale should be used to deny Abbott's Motion to compel production of these documents.

CONCLUSION

For the foregoing reasons, Abbott's Renewed Motion to Compel Production of Evidence Withheld Under the Deliberative Process Privilege should be denied.

Respectfully submitted,

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Dated: April 20, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "MEMORANDUM IN OPPOSITION TO ABBOTT'S MOTION TO COMPEL EVIDENCE WITHHELD UNDER THE DELIBERATIVE PROCESS PRIVILEGE" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: April 20, 2007

/s/ John K. Neal
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